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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/074,959 | 02/12/2002 | Avery J. Evans | SPEC-6150 | 6989 |
| 7590 09/21/2005 | | | EXAMINER | |
| Allegiance Corporation Attn: Kim Diliberti 1430 Waukegan Road McGaw Park, IL 60085-6787 | | | RAMANA, ANURADHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/074,959 | Applicant(s) EVANS ET AL. | |
| | Examiner Anu Ramana | Art Unit 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-16, 21-27 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 10-12, 15-16 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Preissman (US 6,383,190).

Preissman discloses a system for delivery of bone cement including: a plunger assembly with a shaft having a threaded middle section 96 and a handle 92 attached to a first end of the shaft; a dispenser hub assembly having a collar (94d) with an internally threaded portion and a hand grip 94c; and a syringe or "hollow tube" 152 removably engaged with the dispenser hub assembly (Figs. 13-14, 18, col. 8, lines 20-67, col. 9, col. 10, lines 1-36, col. 13, lines 14-67 and col. 14, lines 1-10).

Regarding claims 3 and 30, Preissman discloses that an enlarged introduction section may be provided in the barrel 152 of the syringe to aid in introduction of the plunger without forming a seal (Fig. 21 and col. 17, lines 9-65).

Claims 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Preissman (US 6,383,190).

Preissman discloses a multi-use dispenser kit or "assembly" including: a plunger with a shaft 44 and a handle 38 attached to the shaft 44, a dispenser hub assembly around the shaft, a tube 30 filled with bone cement prior to use of the apparatus, a

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tubing assembly 70 with luer fittings, a cannula 10 and a stylet 1' wherein the shaft 44 is axially displaceable through the tube (col. 16, lines 66-67 and col. 17, lines 1-65).

Claims 21 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Chin (US 5,156,606).

Chin discloses a kit including: a plunger assembly, a dispenser hub assembly 10, a cement cartridge 12 secured thereto and a slap hammer 22 (Fig. 1 and col. 3, lines 34-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of Diesso (US 6,352,585).

Preissman discloses all elements of the claimed invention except for graduations on the disposable syringe 152.

Diesso teaches volume graduation markings on a syringe (col. 8, lines 6-8).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided volume graduation markings on the Preissman syringe to indicate the volume of material contained within.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of Fischer (US 5,603,701).

Preissman discloses all elements of the claimed invention except for handle 92 being ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Preissman apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Preissman (US 6,383,190).

Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Preissman teaches a cement delivery means having a plunger assembly with a shaft and a handle attached to an end of the shaft and a dispenser hub assembly around the shaft (see previous discussion).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Preissman reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US 5,156,606).

Chin discloses tubing assembly 52 connected to hollow tube 12. Chin discloses all elements of the claimed invention except for tubing assembly 52 being removably connected to tube 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have removably connected tubing assembly 52 to tube 12, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on July 1, 2005 have been fully considered.

Applicants' arguments with respect to the rejection of claims 1-2, 4-5, 10, 12-19 are not persuasive for the following reasons. As discussed above, Preissman clearly discloses in Figures 13 and 14, a shaft having a threaded middle section, a handle attached to a first end of the shaft, a dispenser hub assembly including a collar 94d and a hand grip 94c and a syringe or hollow tube 152 removably engaged with the dispenser hub assembly wherein the shaft is axially displaceable through the hollow tube. Regarding the limitation, "pre-filled with bone cement," clearly syringe 152 of Preissman must be filled with bone cement prior to use of the apparatus. Applicants' arguments are directed to an embodiment not utilized for the rejection. A reference is prior art for all that it discloses.

Applicants' arguments with respect to claim 21 are not persuasive for the following reasons. Applicants' are arguing the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Allowable Subject Matter

Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 17-19 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anuadhe Ramana

AR

September 17, 2005


EDUARDO C. ROBERT
PRIMARY EXAMINER